Designation: F2979 – 14

Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses[1]

This standard is issued under the fixed designation F2979; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide specifies a method to measure the *in-vivo* wear of explanted Metal-on-Metal (MoM) and other "hard" (e.g., ceramic) hip components. The guide covers the measurement of acetabular cups and femoral heads using a dimensional change method and is applicable to all prosthetic hip types, including stemmed (modular) and resurfacing hip systems.

1.2 The methods specified in this guide are not applicable for measuring the *in-vivo* wear from non-articulating surfaces, for example modular connections (at the stem/neck, neck/head or cup liner/shell interface) or at acetabular cup rim.

1.3 The parameters (wear depth and volumetric wear) evaluated and reported in this guide are estimated from the assumed as-manufactured shape of the components. The wear volume is calculated using a numerical integration method and the wear depth is the difference between the assumed as-manufactured shape and the measured surface.

1.4 This guide covers the measurement of the depth of wear and the volumetric wear using a Coordinate Measuring Machine (CMM) and the depth of wear using an Roundness Machine. Other metrology measurement equipment may be used to measure the wear depth or volume if the resolution and accuracy of the measurements are comparable with the instruments detailed in this standard. The measurement and analysis protocols should be based on those described in this standard.

1.5 This guide is applicable to hip joints which are nominally spherical at the time of manufacture. Form deviations resulting from manufacturing or deformation may occur and may necessitate the use of a non-spherical surface to represent the unworn surface of the component. Hip joints designed with asymmetry are considered beyond the scope of this guide, although the principles and techniques may be applicable to the characterization of wear from the articulating surfaces.

1.6 This guide is intended as an extension to ASTM F561 as a Stage II nondestructive test.

1.7 *This standard may involve hazardous materials, operations and equipment. As a precautionary measure, explanted devices should be sterilized or disinfected by an appropriate means that does not adversely affect the implant or the associated tissue that may be the subject of subsequent analysis. A detailed discussion of precautions to be used in handling human tissues can be found in ISO 12891-1. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials

2.2 *ISO Standard:*[3]

ISO 12181-1-2003 Part 1 – Geometrical product specifications roundness, vocabulary and parameters of roundness

3. Terminology

3.1 *Definitions:*

3.1.1 For the purposes of this standard the following definitions shall apply.

3.1.2 *cup rim*—the circle formed by the intersection of the articulating surface and the plane normal to the revolution axis that lies coincident with the extreme point of the open cup face.

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

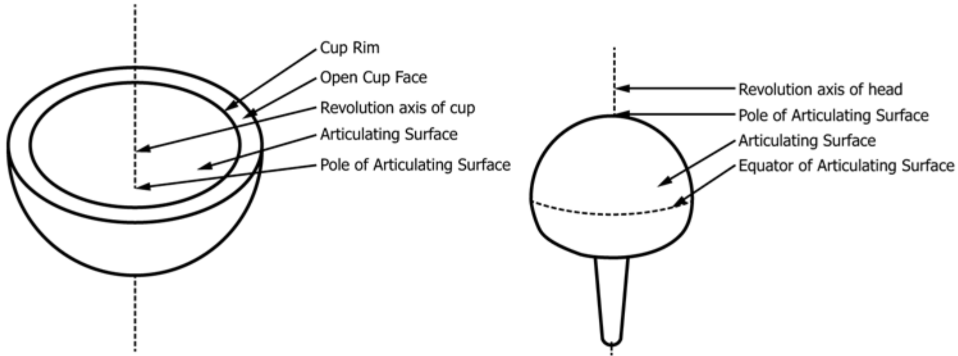

FIG. 1 Schematic Diagram Terminology for Head and Cup Geometry

3.1.3 *edge wear*—the pattern of wear observed in acetabular cups in which the maximum wear depth occurs at the cup rim and progressively deceases along a path from the cup rim to the pole (**1-3**).[4]

3.1.4 *equator of the articulating surface*—the equator of the articulating surface is the circle normal to the revolution axis of the component and to the spherical articulating surface.

3.1.5 *form deviations*—deviations from the nominal designed spherical shape of the hip implants that are not the result of wear. Form deviations shall be separated from wear by the analysis and measurement protocol to prevent errors in the calculated wear. Form deviations may result from manufacturing tolerances or deformation during implantation or revision procedures. Typically, hip implants are symmetrical around the revolution axis.

3.1.6 *maximum inscribed circle*—the reference circle of maximum radius that is totally enclosed by the measured profile. **ISO 12181-1-2003**

3.1.7 *minimum circumscribed arc*—the reference arc of the minimum radius that totally encloses the measured profile. **ISO 12181-1-2003**

3.1.8 *pole of articulating surface*—the pole of an articulating surface is defined by a point at the intercept of the revolution axis of the component and the spherical articulation surface.

3.1.9 *root mean square error*—the statistical measure of the magnitude of the variation between the assumed manufactured component shape fitted to the unworn regions and the measured data points in the unworn regions.

$$RMS\ Error = \left(1/n\ \Sigma\ x_n^2\right)^{\frac{1}{2}} \quad (1)$$

where:

x = the deviation between the assumed shape and each measured data point for n data points.

3.1.10 *volumetric wear*—the volume of material removed from the articulating surface as a result of *in-vivo* wear.

3.1.11 *wear*—deviations from the as-manufactured shape due to loss of material from the articulating surfaces of the components through abrasive, adhesive, or fatigue wear mechanisms, or by corrosion, or any combination of these mechanisms.

3.1.12 *wear depth*—the maximum penetration normal to the articulating surface due to *in-vivo* wear.

3.1.13 *wear rate*—the volumetric wear rate (mm^3/year) or the penetration wear rate (mm/year) is calculated by dividing the wear volume or maximum wear depth by the time implanted in years. The wear rate is an average of the wear over the life of the component. The wear rate of hip joints may change over the life of component with an initial "running in" or "bedding-in" wear rate and the subsequent lower "steady state" wear rate (**4**).

4. Measurement Preparation

4.1 All components shall be cleaned in accordance with the procedure detailed in ASTM F561. Ensure that there are no deposits on the articulating surface of the components that might interfere with or induce errors in the measurements.

4.2 The temperature of the analysis laboratory shall be maintained at 20°C ± 2°C. The components shall be maintained at the temperature of the analysis laboratory for at least 24 hours before the measurement to ensure dimensional stability.

4.3 *Apparatus*—3D Coordinate measuring machine with a maximum permissible error of 2 µm over the largest dimension of the component, or a computer numerical control (CNC) controlled Roundness Machine with automated centering and leveling. The maximum runout of the air-bearing spindle shall be ± 20 nm, and the minimum gauge resolution shall be ± 30 nm.

NOTE 1—When centering and leveling to align the component coordinate system with the machine coordinate system, care must be taken to reference from unworn regions of the component.

5. Measurement of Components Using a Coordinate Measuring Machine

5.1 *Measurement of Acetabular Cup:*

5.1.1 Align the origin of CMM coordinate system with the center of the articulating surface of the component, and the horizontal plane of the coordinate system parallel to the plane of the cup rim. Nondestructively mark the retrieved component, or identify a landmark feature to provide an

[4] The boldface numbers in parentheses refer to the list of references at the end of this standard.

angular reference around the axis of rotational symmetry, so that the measured wear location can be co-registered with the position on the actual component.

5.1.2 Measure data points from the bearing surface so that the maximum spacing between the data points along lines of latitude or longitude is not greater than 0.5 mm (**5**) as shown in Fig. 2. The mesh may be applied and profiles measured in a latitudinal or longitudinal pattern, or a combination to give the optimum point spacing over the component. The distance between the measured data points and the cup rim shall not be greater than 1 mm.

NOTE 2—The 0.5 mm mesh spacing is based on minimizing the errors of calculating the wear volume when using a simple linear "triangulation" integration method to calculate the wear volume (**5**). A larger point spacing may be used if a sensitivity analysis is carried out to investigate the effect of mesh spacing on the wear depth and volume, and the values can be shown to converge.

5.2 *Measurement of Femoral Head:*

5.2.1 Align the origin of the CMM coordinate system with the center of the unworn regions of the articulating surface of the component, with the revolution axis of the head perpendicular to the coordinate system horizontal plane. Nondestructively mark the retrieved component, or identify a landmark feature to provide an angular reference around the axis of rotational symmetry.

5.2.2 Measure data points from the bearing surface so that the maximum spacing between the data points along the lines of latitude or longitude is not greater than 0.5 mm as shown in Fig. 3(**5**). The mesh may be applied in a latitudinal or longitudinal mesh pattern, or a combination to give the optimum point spacing over the component. The measured data points may be extended below the equator to ensure that the whole wear scar is captured in the measurement.

NOTE 3—The 0.5 mm mesh spacing is based on minimizing the errors of calculating the wear volume when using a simple linear "triangulation" integration method to calculate the wear volume (**5**). A larger point spacing may be used if a sensitivity analysis is carried out to investigate the effect of mesh spacing on the wear depth and volume, and the values can be shown to converge.

6. Analysis of CMM Measurements

6.1 Fit the assumed unworn shape of the component. Published studies have used ellipsoids, spheres or nurbs profiles (**6-13**) to represent the unworn (but possible deformed) shape of the hip component. The assumed unworn shape should be fitted to the measured data points in the unworn regions, excluding the data points that are within the worn region. Several of the published methods use a two stage or an iterative process to fit the surface and exclude worn regions from the surface fit (**6-13**).

NOTE 4—ASTM F2033 specifies that the maximum departure from roundness for metallic components shall not be greater than 5 µm for the acetabular component and 5 µm for the femoral component using a least squares or Minimum Zone Centre Method. Due to these deviations, and possible deformation during implantation or revision procedures, fitting a sphere to the unworn data points might result in significant errors in the calculated wear values. In some cases, ellipsoids and other shapes have been shown to better represent the unworn shape of MoM hip components than a simple sphere (**10**).

6.2 Check the fit of the assumed unworn shape by calculating the Root Mean Square (RMS) error between the assumed unworn shape and the measured data points in the unworn region of the hip component (**9**). If the calculated RMS error exceeds 2 µm, the fit and the assumed shape shall be modified to reduce the error.

6.3 Visually check the fit of the assumed unworn shape by looking at a graphical illustration of the deviations from the assumed unworn shape in the unworn regions of the component. The color scale should be set to optimize these deviations, not the appearance of the worn regions.

6.4 If the wear area is not wholly captured within the measurement region and extends below the equator of the head then the measurement shall be repeated to include the whole area of the wear area.

6.5 The maximum depth of wear shall be taken as the maximum deviation between a point on the measured worn surface and a point on the assumed unworn articular surface along a line normal to the assumed unworn articular surface.

6.6 Use a numerical method to calculate the wear volume over the worn regions of the component by calculating the volume between the assumed unworn shape of the component and the worn region.

NOTE 5—Differences in algorithms used to calculate the wear volume may result in variations in the wear volumes. Scratching, indentations and deformation attributed to the explantation process and/or handling after

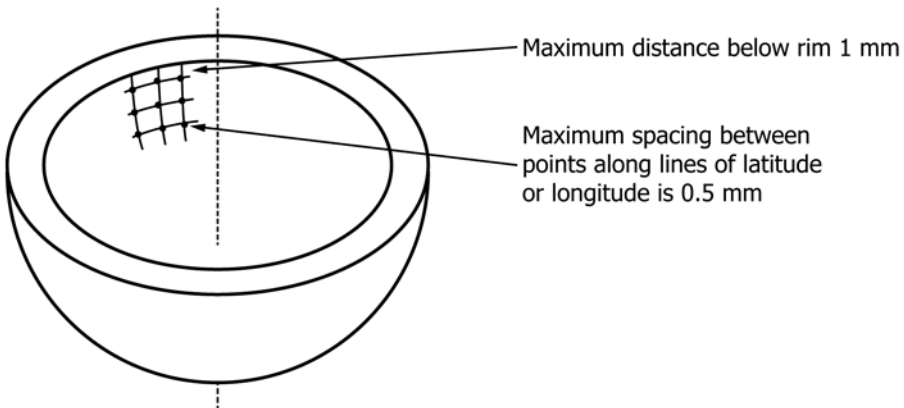

FIG. 2 Schematic Diagram Showing Pattern of Data Points for CMM Measurement of the Acetabular Cup